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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,930	04/18/2005	Michael R Boyd	232046	2078

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EXAMINER	
RAHMANI, NILOOFAR	
ART UNIT	**PAPER NUMBER**
1625	

DATE MAILED: 02/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/521,930	BOYD ET AL.	
	Examiner	Art Unit	
	Niloofar Rahmani	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *10-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-22 are pending.

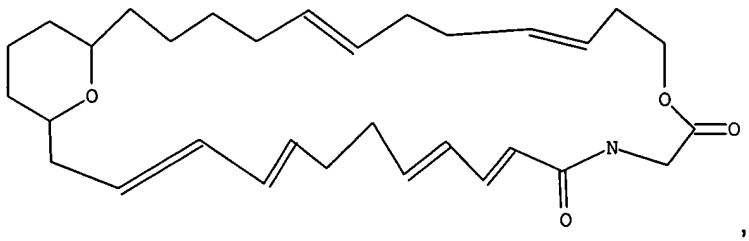
Applicant's election with traverse of group I in the reply filed on 12/05/2005 is acknowledged. The applicant's traverse is on two grounds as followed:

1. The pending claims have in common a special technical feature, which defines the contribution that each claim makes over the prior art. For example, all of the pending claims include compounds of Formula (I).

2. The fact that the subject matter of Groups II, III, and IV substantially overlaps with the subject matter of Group I is at least prima facie evidence that there would be no undue burden on the examiner to examine the claims of Groups I-IV together.

Applicant's argument is not persuasive for the following reasons:

1. The special technical feature of the instant claim is this common core



, because it is the only thing that does not change between group I-IV. Rashid et al. show the same common core (page 3295 and page 3293 on the abstract), therefore, the instant claims do not have the special technical feature. Therefore, it is not applicant's contribution to the art.

2. Further, Group II and IV, which are drawn to multiple active ingredients, do not overlap with the subject matter of Group I, which is drawn to

single activate ingredient. With the multiple activate ingredients synergistic activity can happen between the multiple active ingredients. Therefore, it is a burden some search.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-9 drawn to compounds of formula (I) of group I are examined. Should the compounds of group I become allowable, and then the corresponding method of treatment (group III) which are claims 11-13, 15, and 17-19 will be rejoined. Claims 10-22 remaining subject matter being drawn to the non-elected invention are withdrawn per 37 CFR 1.142(b).

2. ***Priority***

This application is a 371 of PCT/US03/23290, filed on 07/24/2003, which claims benefit of 60/398,092, file on 07/24/2002.

3. ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rejected because the term "prodrug" is vague and unclear. What is the "prodrug" mean? And where does it attach? Does it attach to amino, oxo,hydroxyl, etc.?

4. ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter, which was not describe in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The specification lacks description of the claims i.e. "prodrug". There is no description for what neither cited of the instant compound of prodrug nor preferred formulation of prodrug. There are many prodrugs available out there. Applicant does not give any preference for any type or any formulation of prodrug. Therefore, the specification lacks description of "prodrug".

5. ***Claim Rejections - 35 USC § 112***

Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for Poecillastrin A, does not reasonably provide enablement for the other compounds of formula (I). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to the rest of the compounds of formula (I) as far as making or using the invention commensurate in scope with these claims.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy

the enablement requirement and whether any necessary experimentation is "undue". These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art, 6) the amount of direction provided by the inventor, 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

1) The breadth of the claims.
2) The nature of the invention,
3) The state of the prior art,
4) The level of one of ordinary skill,
5) The level of predictability in the art,
6) The amount of direction provided by the inventor,
7) The existence of working examples,
8) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The nature of the invention: The instant invention is drawn to compounds of formula (I). The specification enabled only Poecillastrin A, but not the rest of the compounds of formula (I).

The state of the prior art: The prior art only used Poecillastrin A, when tested against four different human tumor cell lines and two murine mast cell lines. (Rashid et al., Organic Letters, vol. 4, pages 3293-3296).

The state of the prior art is that it involves screening in vitro and in vivo to determine which compounds exhibit the desired pharmacological activities (i.e. what compounds can treat which specific disease). There is no absolute

predictability even in view of the seeming high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face.

The predictability in the art: It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher*, 427 F. 2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. In the instant case, the instantly claimed invention is highly unpredictable since one skilled in the art would recognize that Poecillastrin A is coming from sponge but there is not shown that where the rest of the compounds of formula (I) would come from and in which area and what kind of sponges can grow. For example Paclitaxel is one of the compounds for caner treatment and it comes from the specific bark tree in specific area.

Amount of guidance/working examples: Applicant has some guidance or examples for Poecillastrin A to enabling for Vacuolar-Type (H+)-ATPase, and some tumor types. But there is no guidance or examples for the rest of the compounds of formula (I) to be enabled.

The breadth of the claims: The breadth of claims is drawn to the compounds of formula (I). The specification enabled only Poecillastrin A, but not the rest of the compounds of formula (I) and how to make them from sponge and which part of the world to grow them.

The quantity of undue experimentation needed: Since the guidance and teaching provided by the specification is insufficient for the compounds of formula (I), one of ordinary skill in the art, even with high level of skill, is unable to use the instant compounds as claimed without undue experimentation.

The level of the skill in the art: The level of skill in the art is high. However, due to the unpredictability in the pharmaceutical art, it is noted that each embodiment of the invention is required to be individually assessed for physiological activity by in vitro and in vivo screening to determine which compounds exhibit the desired pharmacological activity and which diseases would benefit from this activity.

Taking all of the above into consideration, it is not seen where the instant claims 1-9, for the compounds of formula (I), have been enabled by the instant specification.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Niloofar Rahmani whose telephone number is 571-272-4329. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or public PAIR. Status information for unpublished applications is available through Private

PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NILOOFAR RAHMANI
02/08/2006
NR

D.MARGARET SEAMAN
PRIMARY EXAMINER
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